

Remarks

The above-identified application has been carefully reviewed in light of the Examiner's office action mailed on July 18, 2007, which included final rejections of all the claims presented, and the Advisory Action mailed September 25, 2007 in which the Examiner maintained the rejections. Submitted herewith is a Request for Extension of Time, and required fee, extending the period for responding to the Office Action to and including October 25, 2007.

Submitted herewith is a Request for Continued Examination (RCE) and required fee.

Applicant has reviewed and corrected (as indicated below) the specification as requested by the Examiner. Therefore, applicant respectfully requests the Examiner to withdraw the objection to the specification.

The first paragraph on page 16 of the specification has been amended to correct a typographical error. Specifically, the reference numeral "226" has been deleted and replaced by --126--. This amendment is fully supported by the present specification, as filed, for example, the context of the first full paragraph of page 16 and Fig. 7.

Without conceding the correctness of any of the Examiner's rejections, applicant has amended the present claims to facilitate the prosecution and allowance of the above-identified application. Applicant expressly reserves the right to seek patent protection for the original claims and for any other claims that are supported by the present specification in one or more later-filed related applications.

Specifically, independent claim 33 has been amended to recite providing a woman experiencing a hot flash associated with menopause or prone to experiencing hot flashes associated with menopause with at least one cooling device in a package having instructions to remove the cooling device from the package and to place the cooling device at a location on the upper back of the woman to thereby treat the hot flash associated with menopause. Claims 44 and 45 have been amended to be consistent with the amendments to claim 33. Independent claim 55 has been amended to recite the step of removing a cooling device from a package having instructions for treating hot flashes associated with menopause using the cooling device on an upper back of a woman. Claims 57 and 58 have been amended to be consistent with claim 55. Independent claim 61 has been amended to recite removing a cooling device from a package having instructions to place the cooling device at a location on an upper back of a woman experiencing a hot flash associated with menopause or prone to experiencing hot flashes associated with menopause. Claims 63 and 64 have been amended to be consistent with claim 61.

New claims 67-70 have been added and are directed to embodiments for which patent protection is sought.

Claims 39, 60 and 66 have been cancelled, without prejudice.

The amendments to the claims and the new claims are fully supported by the present specification, for example, at page 9, line 32 to page 10, line 6; page 17, lines 4-27; Fig. 1 and the description thereof, and other portions of the specification.

In view of the cancellation of claims 39, 60 and 66, applicant respectfully requests the Examiner to withdraw the rejections of claims 39, 60 and 66 under 35 U.S.C. 112, first paragraph, and 35 U.S.C. 103(a) as being moot.

Claims 33, 35, 36, 38, 41, 44, 45, 55-59 and 61-65 have been rejected under 35 U.S.C. 103(a) as being unpatentable (1) over the Presentation of Kobayashi Healthcare, Inc. (Kobayashi), in view of any of JP 2002119529 (JP '529) or U.S. Patent No. 6,224,899 (U.S. '899); and (2) over JP '529 or U.S. '899 each in view of U.S. Patent No. 5,730,957 (U.S. '957). Applicant vigorously traverses these rejections as they pertain to present claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65 and 67-70.

The present invention is directed to methods of treating hot flashes associated with menopause in a woman.

Independent claim 33 defines embodiments of the invention which comprise providing a woman experiencing a hot flash associated with menopause or prone to experiencing hot flashes associated with menopause with at least one cooling device in a package having instructions to remove the at least one cooling device from the package and to place the at least one cooling device at a location on the upper back of the woman to thereby treat the hot flash associated with menopause.

Independent claim 55 defines embodiments of the invention which comprise removing a cooling device from a package having instructions for treating hot flashes associated with menopause using the cooling device on an upper back of a woman, and thereafter placing the cooling device at a location on an upper back of a woman who is experiencing a hot flash associated with menopause or is prone to experiencing hot flashes associated

with menopause, the cooling device comprising a water-containing gel.

Independent claim 61 defines embodiments of the invention which comprise removing a cooling device from a package having instructions to place the cooling device at a location on an upper back of a woman experiencing a hot flash associated with menopause or prone to experiencing hot flashes associated with menopause, and placing the cooling device at a location on an upper back of a woman who is experiencing a hot flash associated with menopause or is prone to experiencing hot flashes associated with menopause.

A hot flash associated with menopause is often experienced as a wave-like warming sensation throughout a woman's body, for example, radiating from the front of the chest. This wave-like warming sensation can be highly unpleasant, even embarrassing due to a flushing of the face. Applicant, and applicant alone, has discovered that, by placing a cooling device specifically at a location on an upper back of a woman experiencing a hot flash or prone to experiencing hot flashes, the hot flash can be successfully treated, for example, the wave-like warming sensation and the flushing of the face are significantly lessened in intensity or even eliminated.

Applicant has surprisingly and unexpectedly found that placing a cooling device at a location on the upper back, for example, at a region in proximity to the cervical and thoracic vertebrae, such as between the C3 vertebrae and the T6 vertebrae, of a woman experiencing a hot flash or prone to experiencing hot flashes, for example, during the hot flash or in anticipation of a hot flash, that the hot flash is

effectively and advantageously prevented from spreading throughout the woman's body. This is a surprising and unexpected advantage of practicing applicant's invention, as recited in the present claims.

New claims 67-70 more specifically recite aspects of this surprising and unexpected advantage of the present invention.

Further, and importantly the claimed methods allow a woman to easily and discreetly treat menopausal hot flashes at virtually any time, no matter where the woman is or what she is doing. For example, application of the cooling device at a location on an upper back is very effective in reducing or eliminating the hot flash symptoms, such as preventing the hot flash from spreading throughout the woman's body, and, in addition, because the upper back is a discreet location of the body, advantageously facilitates privacy in that the cooling device located on the upper back can be discreetly concealed under clothing. Thus, the present methods very effectively treat menopausal hot flashes, such as preventing the hot flash from spreading throughout the woman's body, and do so discreetly, without embarrassing the woman. This surprising and unexpected combination of advantages, that is effective and successful treatment of menopausal hot flashes, such as preventing the hot flash from spreading throughout the woman's body, in a discreet manner while respecting the woman's privacy and allowing the woman to carry on with her normal activities, achieved in accordance with the present invention, gives the woman more comfort and more confidence during an especially difficult time in her life.

Kobayashi does not disclose, teach or suggest the present invention. For example, Kobayashi does not disclose, teach, or even suggest a method of treating hot flashes associated with menopause in a woman comprising providing a woman experiencing a hot flash associated with menopause or prone to experiencing hot flashes associated with menopause with at least one cooling device in a package having instructions to remove the at least one cooling device from the package and to place the at least one cooling device at a location on the upper back of the woman to thereby treat the hot flash associated with menopause, as recited in claim 33.

Further, Kobayashi does not disclose, teach or even suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises removing a cooling device, comprising a water-containing gel, from a package having instructions for treating hot flashes associated with menopause using the cooling device on an upper back of a woman; and, thereafter placing the cooling device at a location on an upper back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, as recited in claim 55.

In addition, Kobayashi does not disclose, teach or even suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises the steps of removing a cooling device from a package having instructions to place the cooling device at a location on an upper back of a woman experiencing a hot flash associated with menopause or prone to experiencing hot flashes associated with menopause, and placing the cooling device removed from the package at a location on an upper back of a woman who is experiencing a hot

flash or is prone to experiencing hot flashes, as recited in claim 61.

As recognized by the Examiner, Kobayashi does not disclose, teach or even suggest instructing a user to place the cooling device on any specific site, let alone at a location on the upper back of the woman, as recited in the present claims. Moreover, Kobayashi does not even recognize or even suggest the surprising, unexpected combination of advantages, that is effective and successful treatment of menopausal hot flashes, such as preventing the hot flash from spreading throughout the woman's body, in a discreet manner while respecting the woman's privacy and allowing the woman to conduct her normal activities, achieved in accordance with the present invention. The present claims and the surprising and unexpected advantages achieved by applicant are unpredictable from the deficient teachings of Kobayashi.

Kobayashi is grossly deficient with respect to the present claims. Only after knowing of applicant's disclosure and invention would one of ordinary skill in the art even consider the present methods, let alone do so and expect to obtain the surprising, unexpected and unpredictable combination of advantages achieved only by applicant. Thus, applicant submits that the rejections based on Kobayashi are improper and must be withdrawn since they are derived from an improper hindsight view of applicant's own disclosure and invention.

In view of the above, applicant submits that Kobayashi provides no motivation, nor any common sense or other rational basis, for making obvious the present invention, and obtaining

the surprising, unexpected and unpredictable combination of advantages achieved only by applicant.

JP '529 does not disclose, teach or suggest the present invention. For example, JP '529 does not disclose, teach or even suggest any methods for treating hot flashes associated with menopause in a woman, let alone methods for treating hot flashes associated with menopause in a woman experiencing such a hot flash or prone to experiencing hot flashes associated with menopause including providing a woman experiencing a hot flash or prone to experiencing hot flashes with a cooling device in a package having instructions to place a cooling device at a location on her upper back to thereby treat the hot flash (claim 33) or placing a cooling device at a location on the upper back of the woman (claims 55 and 61), as recited in the present claims.

U.S. '899 does not disclose, teach or suggest the present invention. For example, U.S. '899, like JP '529, does not disclose, teach or even suggest any methods for treating hot flashes associated with menopause in a woman, let alone methods of treating hot flashes associated with menopause in a woman experiencing such a hot flash or prone to experiencing hot flashes associated with menopause comprising providing a woman experiencing a hot flash or prone to experiencing hot flashes with a cooling device in a package having instructions to place the cooling device at a location on her upper back or placing a cooling device at a location on the upper back of the woman, as recited in the present claims.

U.S. '957 does not disclose, teach or suggest the present invention. For example, U.S. '957 does not disclose, teach or even suggest methods for treating hot flashes associated with menopause in a woman experiencing such a hot flash or prone to experiencing hot flashes associated with menopause comprising providing a woman experiencing a hot flash or prone to experiencing hot flashes with a cooling device in a package having instructions to place a cooling device at a location on her upper back or placing a cooling device at a location on the upper back of the woman, as recited in the present claims.

Like Kobayashi, none of JP '529, U.S. '899 and U.S. '957 even recognize or even suggest the surprising, unexpected and unpredictable combination of advantages, that is effective and successful treatment of menopausal hot flashes, such as preventing the hot flash from spreading throughout the woman's body, in a discreet manner while respecting the woman's privacy and allowing the woman to conduct her normal activities, achieved in accordance with the present invention. Also like Kobayashi, JP '529, U.S. '899 and U.S. '957 are all grossly deficient with regard to the present claims.

Still further, in stating the present prior art rejections, the Examiner never even mentions a package having instructions to place a cooling device at a location on an upper back of a woman, or placing a cooling device at a location on the upper back of the woman experiencing a hot flash or prone to experiencing hot flashes associated with menopause, as recited in all of the present claims. This is so because none of the prior art even suggest providing such a package to place or placing a cooling device at a location on the upper back of, a

woman experiencing a hot flash or prone to experiencing hot flashes. This is an important limitation in all of the present claims, and is not disclosed, is not taught, is not recognized and is not even suggested by any of the prior art.

The Examiner seeks to remedy this clear deficiency of the prior art by ignoring it. The Examiner states that it is expected that the patch will be applied to the site of origin of hot flashes as disclosed by applicant on page 9, lines 1-5 of the present specification. Applicant vigorously objects to this blatant reliance on applicant's own disclosure to reject applicant's claims. This is improper.

It is important to note that none of the prior art cited by the Examiner teaches the use of a cooling device at the site of origin of hot flashes.

Most importantly, the Examiner is blatantly relying on applicant's own disclosure to reject applicant's own claims. This improper reliance is repeated in the Examiner's comments in the above-noted Advisory Action. The Examiner clearly and repeatedly relies on applicant's disclosure to reject the present claims. Such reliance on applicant's own disclosure to reject applicant's own claims is tantamount to rejecting the present claims based on the above-identified application. With all due respect, such a rejection makes no sense. Such blatant reliance on applicant's own disclosure is clearly an improper hindsight basis for rejecting the present claims. To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the

D-3150
10/576,803

inventor taught is used against the teacher. W.L. Gore & Associates v. Garlock, Inc., 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983).

The Examiner, apparently in an attempt to locate some reference to the "upper back of the woman", provides a pamphlet on a "BeKool soft gel sheet product", which the Examiner apparently located on March 19, 2007.

This "BeKool" pamphlet is not prior art against the present claims, and the Examiner does not claim that the "BeKool pamphlet" is prior art. For example, in citing the "BeKool" pamphlet in the PTO-892 form provided with the Office Action mailed July 18, 2007, the Examiner did not list a date for this pamphlet. The Examiner asserts that BeKool soft gel sheet product was available since 2003. The pamphlet provided by the Examiner provides no evidence in this regard.

The present specification, at page 2, acknowledges the existence of an adhesive cooling composition shaped into a sheet, and coolers carried in a woman's purse so that when a hot flash occurs, the cooler is removed from her purse and slid onto the woman's wrist.

Neither this deficient prior art acknowledged by applicant nor the non-prior art "BeKool pamphlet" provided by the Examiner render the present claims unpatentable.

The prior art coolers acknowledged by applicant do not disclose, teach or even suggest placing the coolers on the upper back of a woman experiencing or prone to experiencing a hot flash associated with menopause to treat the menopausal hot flash, let alone obtaining the surprising, unexpected and unpredictable combination of advantages, for example, preventing

the menopausal hot flash from spreading throughout the woman's body, as achieved by applicant in accordance with the present invention.

In addition, the above-identified application has been made special because of infringement activities. Thus, it is not surprising that the non-prior art "BeKool pamphlet" exists and is directed to embodiments of the present invention.

In any event, the non-prior art "BeKool pamphlet" cannot properly be used to render the present claims unpatentable.

The Examiner concludes that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103(a). Applicant disagrees based on the MPEP's definition of *prima facie* obviousness.

As set forth in MPEP § 2143, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Simply put, in the present situation the prior art does not disclose, teach or even suggest all of the limitations in the present claims, for example, does not disclose, teach or even suggest the "at a location on the upper back" limitation of the

present claims. This fact is made all the more clear by the Examiner's explanation of the rejections which does not even mention the "at a location on the upper back" limitation; by the Examiner's blatant and improper hindsight reliance on applicant's own disclosure; and by the Examiner's improper citing of the non-prior art "BeKool pamphlet".

Moreover, none of the prior art, taken singly or in combination, disclose, teach or even suggest the surprising, unexpected and unpredictable combination of advantages, that is effective and successful treatment of menopausal hot flashes, including preventing the menopausal hot flash from spreading throughout the body of the woman, in a discreet manner while respecting the woman's privacy and allowing the woman to conduct her normal activities, achieved by applicant, and only applicant, in accordance with the present claims.

There simply is no motivation, no common sense basis and no other rational basis for one of ordinary skill in the art to combine and extend the deficient teachings of the prior art to make obvious the presently claimed methods and obtain the surprising, unexpected and unpredictable combination of advantages of such methods achieved by, and only by, applicant.

Only after knowing of applicant's disclosure and invention would one of ordinary skill in the art practice the present methods, including instructing a woman experiencing a menopausal hot flash or prone to experiencing menopausal hot flashes to place, or placing, a cooling device on the upper back of the woman and expect to obtain, let alone obtain the unexpected, surprising and unpredictable combination of advantages achieved by applicant and applicant alone.

In view of the above, and contrary to the Examiner's contention, applicant submits that no prima facie obviousness case has been made out by the Examiner, and that no prima facie obviousness case exists with regard to the present claims.

Treatment of a localized lesion, bruise or sprain by applying a cooling patch to the site of the lesion, bruise or sprain, as disclosed in JP '529, is not in the least suggestive of treating a woman experiencing a menopausal hot flash or prone to experiencing menopausal hot flashes by instructing the woman to place a cooling device at a location on her upper back or placing a cooling device at a location on her upper back, as recited in the present claims. Menopausal hot flashes can affect a woman's entire body and, therefore, can be considered a systemic condition. Thus, treatment of local traumas or local conditions, as in JP '529, is not even suggestive of treating menopausal hot flashes.

Neither Kobayashi nor JP '529, alone or in combination, discloses, teaches or even suggests a method of treating hot flashes associated with menopause in a woman experiencing a hot flash or prone to experiencing such hot flashes, which method comprises instructing the woman to place a cooling device at a location on her upper back or placing a cooling device at a location on the upper back of the woman, as recited in the present claims.

In view of the above, applicant submits that the present claims, and in particular claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59 and 61-70 are unobvious from and patentable over Kobayashi in view of JP '529, under 35 U.S.C. 103.

Further, U.S. '899 does not supply the substantial deficiencies apparent in Kobayashi with regard to the present claims.

As discussed hereinabove with regard to JP '529, applying a cooling device to a specific site, as taught in U.S. '899, in order to treat the specific site is not even remotely suggestive of methods of treating hot flashes associated with menopause in a woman experiencing a menopausal hot flash or prone to experiencing such hot flashes comprising instructing the woman to place a cooling device at a location on her upper back or placing a cooling device at a location on the upper back of the woman, as recited in the present claims, let alone doing so and obtaining the surprising, unexpected and unpredictable combination of advantages achieved by applicant and applicant alone.

Further, U.S. '899's treatment of feverish subjects, which involves placing a cooling composition on a forehead of a person who is feverish, is not even remotely suggestive of methods of treating hot flashes associated with menopause in a woman comprising instructing the woman to place a cooling device at a location on her upper back or placing a cooling device at a location on the upper back of the woman, as recited in the present claims.

Neither Kobayashi nor U.S. '899, alone or in combination, discloses, teaches or even suggests a method of treating hot flashes associated with menopause in a woman experiencing such a hot flash or prone to experiencing such hot flashes comprising instructing the woman to place a cooling device at a location on her upper back or placing a cooling device at a location on the

upper back of the woman, as recited in the present claims, let alone obtaining the surprising, unexpected and unpredictable combination of advantages of practicing the present claims achieved by applicant and applicant alone.

In view of the above, applicant submits that the present claims, and in particular claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59 and 61-70, are unobvious from and patentable over Kobayashi in view of U.S. '899 under 35 U.S.C. 103.

The Examiner cites U.S. '957, which suggests a cool spray can be used to treat a wide variety of conditions including sunstroke, sunburn, fever, muscle fatigue and hot flashes, as teaching that "the art has recognized using cooling techniques to treat fever, hot flashes and muscle strain equally...in terms of treating them using the same cooling methods and devices."

Applicant submits that even if the art has recognized using cooling techniques to treat a wide variety of conditions, including hot flashes, the art has not recognized or even suggested treating hot flashes associated with menopause in a woman experiencing such a hot flash or prone to experiencing hot flashes comprising instructing the woman to place a cooling device at a location on her upper back or placing a cooling device at a location on the upper back of the woman, let alone obtaining the surprising, unexpected and unpredictable combination of advantages of practicing the present claims achieved by applicant and applicant alone. Moreover, using a spray to treat hot flashes can be downright embarrassing for the menopausal woman and is certainly not as effective for an extended period of time in treating the hot flash, nor as

D-3150
10/576,803

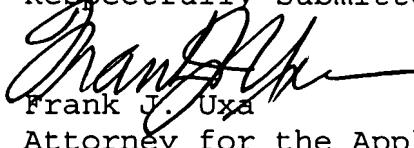
discreet as a cooling device located on the upper back of the woman.

In view of the above, applicant submits that the present claims, and in particular claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59 and 61-70, are unobvious from and patentable over JP '529 and U.S. '899 in view of U.S. '957 under 35 U.S.C. 103.

Applicant submits that each of the present dependent claims is separately patentable over the prior art. For example, the prior art does not disclose, teach or suggest the present apparatus and systems including the addition feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In conclusion, applicant has shown that the present claims, that is, claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, and 61-70, are unobvious from and patentable over the prior art under 35 U.S.C. 103. Therefore, applicant respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call applicant's attorney at the telephone number given below.

Respectfully submitted,



Frank J. Uxa

Attorney for the Applicant

Reg. No. 25,612

Stout, Uxa, Buyan & Mullins, LLP

4 Venture, Suite 300

Irvine, CA 92618

(949) 450-1750

Facsimile (949) 450-1764